

JAN 19 2007

PATENT

Docket No. 275.0010 0101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): MUNN et al.	)	Group Art Unit: 1614
	)	
Serial No.: 10/780,797	)	Examiner: James D. Anderson
Confirmation No.:1508	)	
	)	
Filed: February 17, 2004	)	
	)	
For: USE OF INHIBITORS OF INDOLEAMINE-2, 3-DIOXYGENASE IN COMBINATION WITH OTHER THERAPEUTIC MODALITIES		

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RESPONSE TO RESTRICTION REQUIREMENT  
AND SPECIES ELECTION

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Restriction Requirement mailed December 20, 2006, Applicants elect, with traverse, Group I (claims 1-14 and 33), drawn to method of treating cancer comprising administering an inhibitor of indoleamine-2,3-dioxygenase *and* at least one additional therapeutic agent. Applicants submit that claims 19 and 24-31 are also drawn to a method of treating cancer comprising administering an inhibitor of indoleamine-2,3-dioxygenase *and* at least one additional therapeutic agent, and properly belong in Group I.

Applicants' Representatives reserve the right to pursue examination of the non-elected claims in continuation or divisional applications. Applicants respectfully request reconsideration of the restrictions in this case and submit that the inventions as claimed can be readily evaluated in one search without placing undue burden on the Examiner.

Applicants request the rejoinder of Groups I, III (claims 32 and 34), IV (claims 35 and 37), and V (claim 36). Elected Group I is drawn to method of treating cancer comprising administering an inhibitor of indoleamine-2,3-dioxygenase *and* at least one additional therapeutic agent. Claims 32, 34, 35, and 37 are drawn to a method of "augmenting the rejection of tumor cells" comprising administering an inhibitor of indoleamine-2,3-dioxygenase *and* at least one

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additional therapeutic agent. Applicants submit that the burden to search and examine a method of augmenting the rejection of tumor cells along with the elected method of treating cancer is not unduly burdensome.

Claim 36 (Group V) is drawn to a method of treating cancer comprising administering an inhibitor of indoleamine-2,3-dioxygenase *and* radiation therapy. Applicants submit that radiation therapy is an example of an additional therapeutic agent (see, for example, claim 5) and submit that Group I is generic to claim 36. This is acknowledged by the Examiner, that "chemotherapeutic agents or radiation" are species of the "additional therapeutic agent" ( see pages 6 and page 10 of Restriction Requirement mailed December 20, 2006). In fact, Applicants do not understand the Examiner's position that administering an inhibitor of indoleamine-2,3-dioxygenase *and* radiation therapy is both a separate Restriction Group (see, for example, Groups IV and V) and a species.

Likewise, claims 35 and 37 (Group IV) are drawn to a method of augmenting the rejection of tumor cells comprising administering an inhibitor of indoleamine-2,3-dioxygenase *and* radiation therapy. Applicants submit that claims 35-37 properly belong in Group I. Further, Applicants submit that the burden of examining claims 35-37 along with Group I is not undue.

Applicants submit that the burden to search and examine the methods of Groups I, III, IV, and V is not unduly burdensome. Reconsideration and examination of the claims of Groups III, IV, and IV along with the claims of I is respectfully requested.

On page 4 of the Restriction Requirement mailed December 20, 2006, the Examiner asserted that "the claims of Groups IV/V require administration of an inhibitor of indoleamine-2,3-dioxygenase and radiation therapy, whereas the claims of Group I/II/III only require administration of [an] inhibitor of indoleamine-2,3-dioxygenase" (emphasis in original). Applicants respectfully submit that this statement is incorrect. Applicants submit that Groups I and III are drawn to the administration of an inhibitor of indoleamine-2,3-dioxygenase *and* at least one additional therapeutic agent.

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In regard to the Election of Species requirements, Applicants elect, with traverse:

- A) 1-methyl-tryptophan;
- B) administration of one or more chemotherapeutic agents; and
- C) cyclophosphamide.

With respect to these species elections, these elections are with traverse to the extent that it is understood that (a) the requirement will be withdrawn upon the finding of an allowable genus; and (b) any species withdrawn from consideration will be transferred to the elected subject matter unless it is found patentably distinct from the elected or allowed claims. Applicants traverse on the grounds that the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the Examiner.

Applicants submit that claims 1-7, 10, 13, 14, 19, and 24-37 are generic to elected species A (1-methyl-tryptophan). Applicants submit that the enzyme indoleamine-2,3-dioxygenase (IDO) is well known and characterized (see, for example, page 12, lines 16-18 and page 14, lines 25-20 of the specification) and that a variety of different inhibitors of IDO are known (see, for example, page 14, lines 1-18 of the specification). Thus, Applicants do not understand the Examiner's apparent need for a "common structural core" to search "inhibitors of indoleamine-2,3-dioxygenase" (see page 5, Restriction Requirement mailed December 20, 2006).

Applicants submit that claims 1, 2, 8-14, and 32-33 are generic to elected species B (administration of one or more chemotherapeutic agents).

Applicants submit that claims 1-3, 8-14, and 32-34 are generic to elected species C (cyclophosphamide). Applicants submit that an extensive variety of antineoplastic chemotherapeutic agents are well known and widely used by the skilled artisan (see, for example, page 14, lines 1-18 of the specification). Thus, Applicants do not understand the Examiner's apparent need for a "common structural core" to search and examine "antineoplastic chemotherapeutic agents" (see, for example, page 9, Restriction Requirement mailed December 20, 2006).

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Telephonic interviews were held between Examiner James Anderson and Applicants' Representative, Nancy Johnson, on October 31, 2006, and November 28, 2006, to discuss the Restriction Requirement mailed October 25, 2006. The Examiner is thanked for the courtesy of these teleconferences.

In these conversations, Applicant expressed concern that claims drawn to the treatment of cancer and claims drawn to the treatment of an infection were placed in separate Restriction Groups, yet the Applicant was also required to make an election of species election between the treatment of cancer and the treatment of an infection. Applicants requested clarification as to how the treatment of cancer and the treatment of an infection could be simultaneously considered separate restriction groups and species of one another. Applicants thank the Examiner for reconsidering and vacating the Restriction Requirement mailed October 25, 2006, and replacing it with the Restriction Requirement mailed December 20, 2006. However, Applicants express concern that the present Restriction Requirement repeats the confusion of the previous Restriction Requirement, restricting between methods of treating cancer of treating cancer comprising administering an inhibitor of IDO and at least one additional therapeutic agent (Groups I and III) and methods of treating cancer comprising administering of an inhibitor of IDO and radiation therapy (Groups IV and V), yet requiring an election of species between "additional chemotherapeutic agent" (i.e. chemotherapeutic agent or radiation)" (see page 10, Restriction Requirement mailed December 20, 2006).

Applicants reserve the right to pursue examination of any non-elected claims in continuation or divisional applications.